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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,561	12/12/2003	David James Dooley	PC 25627A	3925
28880	7590	06/07/2006	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			JONES, DWAYNE C	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 06/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,561

Applicant(s)

DOOLEY ET AL.

Examiner

Dwayne C. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the election of 03APR2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/1/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-16 are pending.
2. Claims 1-12 are elected and rejected.
3. Claims 13-16 are non-elected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election with traverse of Group I, corresponding to claims 7-12 and linking claims 1-6 to the extent that they read on treating the disorder of fibromyalgia, in the reply filed on April 3, 2006 is acknowledged. In addition, applicants elected the species of Formula I, where R, R¹, R², R⁴, and R⁶-R⁸ are each hydrogen and R³ and R⁵ are each (C₁-C₆)alkyl, such as methyl. However, this elected species was found in the prior art reference of WO 99/21824. The traversal is on the ground(s) that the groups are not restrictable. This is not found persuasive because the disorders or conditions are independent or distinct and each have distinct etiologies, pathophysiological processes, modes and methods of treatment, as well as patient populations, which would not require the same prior art search for each ailment or condition.
5. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

6. The information disclosure statement filed on June 11, 2004 (3 sheets) has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 7 recite the broad recitation "mammal", and the claims also recite "including a human" which is the narrower statement of the range/limitation.

10. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. The following reasons support this rejection. It is unclear to the skilled artisan as to what specifically the instantly claimed compounds of formula I and IA, is to be used therapeutically for or what is the intended benefit/risk ratio applicable for the claimed compounds of formula I and IA to a medical treatment? In addition, what is meant by the phrase, "therapeutically effective amount"? Moreover, this ambiguous phrase does not clearly state what is to be therapeutically effected with a dose of the compounds of formulas I and IA. This rejection could be obviated with the incorporation of the following phrase or equivalent "for treating the disorder of fibromyalgia" and in claims 9-12 "for treating the disorder of fibromyalgia and a concomitant disorder" with the administration of the compounds of formula I and IA.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 7-12 and linking claims 1-6 to the extent that they read on treating the disorder of fibromyalgia rejected under 35 U.S.C. 103(a) as being unpatentable over Byrons et al. of WO 99/21824 in view of Beers, M. H. and Berkow, R., Editors-in-Chief, The Merk Manual of Diagnosis and Therapy, 17th Edition, pages 481-482. Byrons et al. teach of employing the cyclic amino acid compounds and their derivatives of the compounds of formulas I and IA, especially when the "[p]referred" variables of R to R¹⁴ are selected from hydrogen and lower alkyl, (see page 2, line 10 to page 3, line 3). In addition, Byrons et al. teach that these cyclic amino acid compounds and their derivatives are useful to treat pain and other ailments, namely depression, anxiety, panic, and gastrointestinal disorders, such as irritable bowel syndrome, (see page 2, lines 1-6). Byrons et al. also recite the "most preferred compounds", which is represented by the compound (3S, 4S)-(1-Aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid, (see page 8, line 21). Byrons et al. are silent to treating the painful ailment of fibromyalgia. The prior art reference of Beers, M. H. and Berkow, R., Editors-in-Chief,

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The Merk Manual of Diagnosis and Therapy, 17th Edition, pages 481-482 teach that the ailment of fibromyalgia is characterized by pain of the fibrous tissues, muscles, tendons, ligaments, and other sites. Beer, M. H. and Berkow, R. also teach that fibromyalgia may be generalized (sometimes associated with a concomitant condition), such as with the symptoms or conditions of poor sleep, anxiety, fatigue, and irritable bowel syndrome, or localized (ie, myofascial pain syndrome), (see page 481). With the combined teachings of Byrns et al. with respect to the compounds and methods of treating pain as well as the Beers, M. H. and Berkow, R. disclosure regarding pain associated with fibromyalgia, one having ordinary skill in the art is motivated to treat pain and for that matter fibromyalgia as shown by the prior art teachings. Clearly, one having ordinary skill and knowledge in the art, would recognize that the pain associated with fibromyalgia would be necessarily treated with the administration of the cyclic amino acid compounds and their derivatives of the compounds of formulas I and IA because Byrns et al. specifically teach that these compounds are effective in the treatment of pain.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,001,876 in view of Beers, M. H. and Berkow, R., Editors-in-Chief, *The Merk Manual of Diagnosis and Therapy*, 17th Edition, pages 481-482. Although the conflicting claims are not identical, they are not patentably distinct from each other because when U.S. Patent No. 6,001,876 teaches of the compounds of formula I, where in particular the variable of R³ is hydrogen and either variable of R² or R¹ is an unsubstituted cycloalkyl of from five to six carbon atoms, for the treatment of pain. The prior art reference of Beers, M. H. and Berkow, R., Editors-in-Chief, *The Merk Manual of Diagnosis and Therapy*, 17th Edition, pages 481-482 teach that the ailment of fibromyalgia is characterized by pain of the fibrous tissues, muscles, tendons, ligaments, and other sites. Beer, M. H. and Berkow, R. also teach that fibromyalgia may be generalized (sometimes associated with a concomitant condition), such as with the symptoms or conditions of poor sleep, anxiety, fatigue, and irritable bowel syndrome, or localized (ie, myofascial pain syndrome), (see page 481). With the combined teachings of U.S. Patent No. 6,001,876 with respect to the compounds and methods of treating pain as well as the Beers, M. H. and Berkow, R. disclosure regarding pain associated with fibromyalgia, one having ordinary skill in

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the art is motivated to treat pain and for that matter fibromyalgia as shown by the prior art teachings. Clearly, one having ordinary skill and knowledge in the art, would recognize that the pain associated with fibromyalgia would be necessarily treated with the administration of the cyclic amino acid compounds and their derivatives of the compounds of formula I, where in particular the variable of R^3 is hydrogen and either variable of R^2 or R^1 is an unsubstituted cycloalkyl of from five to six carbon atoms because U.S. Patent No. 6,001,876 specifically teach that these compounds are effective in the treatment of pain.

17. Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 11 of copending Application No. 10/731,225. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application as well as copending Application No. 10/731,225 teach of treating fibromyalgia with the cyclic amino acid compounds which is evident to the skilled artisan when the compound of formula I from copending Application No. 10/731,225 because these compounds of copending Application No. 10/731,225 are cyclic structures when the variable of R^3 is hydrogen and either variable of R^2 or R^1 is an unsubstituted cycloalkyl of from five to six carbon atoms.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-

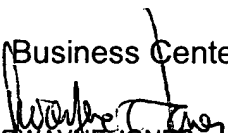
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0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, may be reached at (571) 272-0718. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).


DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
June 4, 2006